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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/751,384 | 01/05/2004 | David John Targell | NGP0039 | 2667 |
| 832 | 7590 | 03/23/2006 | EXAMINER | |
| BAKER & DANIELS LLP 111 E. WAYNE STREET SUITE 800 FORT WAYNE, IN 46802 | | | STIGELL, THEODORE J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3763 | |

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/751,384 | TARGELL, DAVID JOHN | |
| | Examiner | Art Unit | |
| | Theodore J. Stigell | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Parry (5,104,384). See Figures 1-6 and the respective portions of the specification. Parry discloses an accessory device for use with a medical apparatus in which fluid is withdrawn from or expelled into a patient through a hollow needle (2) that includes all of the limitations as recited in claim 1. Parry discloses a device that comprises an elongated hollow body (1,6), a needle (2) connected to the hollow body, a sleeve (3) surrounding the needle, the sleeve reciprocally and movable associated with the hollow body for movement into and out of the hollow body to thereby expose more or less of the needle, the sleeve having a first position (position 20) wherein the sleeve covers the major portion of the needle but does not cover the entire needle, a second position wherein a sufficient portion of the length of the needle is exposed so that it is available for use in a procedure, and a third position (23) wherein the sleeve covers the entire needle and is locked in position to prevent needle-stick injuries, and the sleeve including a track (14a) and the hollow body including stop members (12,14) the stop member (14) operatively guided in the track whereby the sleeve can automatically move from the first

Art Unit: 3763

position to the second position and thereafter to the third position upon insertion of the needle and the stop member (12) automatically and permanently (See column 5, lines 61-65) locks the sleeve in the third position upon withdrawal of the needle.

In regards to claims 2-5, Parry discloses a device that includes all of the limitations as recited in claim 1 wherein the sleeve includes the stop members which can be considered flexible members and the hollow body includes a plurality of tracks.

In regards to claims 6-8, Parry discloses a device that includes all of the limitations as recited in claim 1 wherein the flexible member includes a projection (defined as the distal portion of the member) which engages with the track, and wherein the track includes a first portion to permit the sleeve to move from the first position to the second position and a second portion to permit movement to the third position, and wherein the hollow body includes a stop (33) engaging the stop member (12) when the sleeve reaches the third position.

In regards to claims 9-11, Parry discloses a device that includes all of the limitations as recited in claim 1 wherein the hollow body defines a central axis and the flexible member can move radially inwardly and outwardly relative to the central axis, and further comprising a biasing spring (16) that biases the sleeve toward the third position, and further including a collar (6) operatively associated with the hollow body and sleeve for preventing the sleeve from becoming dissociated.

In regards to claim 12, Parry discloses a device that includes all of the limitations that were previously recited in claim 1 and wherein the flexible fingers (12,14) are

disposed within the hollow body and the fingers remain in the hollow body in the third position.

In regards to claims 13-19, please see the rejections for claims 2-11.

In regards to claims 20-21, please see the rejections for claims 1 and 12.

Claims 12-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Parry (4,813,940). Parry discloses a device comprising an elongated hollow body (10), a needle (9) connected to the hollow body, a sleeve (11) surrounding the needle, the sleeve reciprocally and movably associated with the hollow body for movement into and out of the hollow body to thereby expose more or less of the length of the needle, the sleeve having a first position (19") wherein the sleeve covers a major portion of the needle (See column 2, lines 64-67), a second position wherein the needle is exposed, and a third position (19') wherein the sleeve is locked in a covering position and the sleeve includes flexible finger (19) and the hollow body includes a track (20), the flexible finger disposed within the hollow body and operatively guidedly associated with the track whereby the sleeve can automatically move from a first position to a second position and thereafter to a third position and the flexible finger remaining disposed within the hollow body and locking the sleeve in a third position upon withdrawal of the needle.

In regards to claims 13-15, Parry discloses a device that includes all of the limitations as recited in claim 12 wherein the sleeve includes a plurality of projections (19) and the hollow body includes a plurality of tracks (20), the flexible finger including a projection (distal end of 19) which engages with a track whereby the track guides the

finger, and wherein the track includes a first portion to permit movement between the first and second positions and a second portion to permit movement to the third position.

In regards to claims 16-19, Parry discloses a device that includes all of the limitations as recited in claim 12 wherein the hollow body includes a stop (area near 22) and said flexible finger engages the stop when the sleeve reaches the third position, the hollow body defining a central axis and wherein the flexible finger can move radially inwardly and outwardly relative to the central axis of the hollow body, and further comprising a spring (16) that biases the sleeve into the third position, and further including a collar (distal end of 10) that prevents sleeve from disassociating from the hollow body.

In regards to claim 20, please see previous rejections.

Claims 12-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Asbaghi (5,688,241). In regards to claim 12-13, Asbaghi discloses a device that includes all of the limitation recited. Asbaghi shows an elongated body (20), a needle (14), a sleeve (26) surrounding said needle, the sleeve being movably associated with the outer body and having three positions, the first position with the majority of the needle covered, the second with the needle exposed, and the third with the needle completely covered by the sleeve in a locked position, the outer body including tracks (32) and the sleeve including flexible fingers (36,52) disposed within the hollow body and guided by the tracks, the sleeve automatically movable from the first position to the second position and thereafter to the third position upon insertion into the patient to the

third position and the flexible fingers (36) remain disposed within the hollow body and automatically lock sleeve in the third position upon withdrawal of the needle from the patient.

In regards to claims 14-15, Asbaghi discloses a device as recited in claim 12 wherein the flexible fingers (36) include projections defined as the top portion of the finger that interacts with the track, and the tracks include a first portion (62) and a second portion (66).

In regards to claims 16-19, Asbaghi discloses a device as recited in claim 12 wherein the body includes a stop defined as the inner surface of the collar (42), the flexible fingers can move radially inward and outward if pressure is applied, and a spring (54) is included to bias the sleeve in the first position.

In regards to claim 20, please see previous rejection.

Response to Arguments

Applicant's arguments filed 2/24/2006 have been fully considered but they are not persuasive. In response to the Applicant's arguments that Asbaghi does not disclose, " a flexible finger disposed within the hollow body" and "the finger remains disposed within the hollow body" and locks the sleeve into the third position, the Examiner respectfully disagrees. The Examiner has used element (36) and not just element (52) to define the "flexible finger". It is clear from the figures and specification that element (36) is disposed within the hollow body and remains disposed within the

Art Unit: 3763

hollow body and locks the sleeve in the third position. Element (36) provides a locking function for preventing the sleeve from being removed from the hollow body.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Theodore J. Stigell

